#### **REMARKS**

# Summary of the Office action

Claims 30, 31, 33, 35, 36, 38, 64-76, 78, 80, and 82-88 are pending. Each of the claims is rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. The rejection is addressed as follows.

## Attorney docket number

The attorney docket number for this application has changed to 08338/028006.

Applicants respectfully request that the Office refer to this docket number in future correspondences.

## Rejection under 35 U.S.C. § 112, first paragraph

Claims 30, 31, 33, 35, 36, 38, 64-76, 78, 80, and 82-88 are rejected under 35

U.S.C. § 112, first paragraph, for lack of enablement. The Office continues to reject the claims for failing to comply with the enablement requirement, as set forth in the Office action of October 15, 2004 for disclosing methods of treatment. According to the Office, Applicants' amendment of claim 30 from a "method of treating a patient" to a "method of introducing stem cells into a patient" fails to overcome the enablement rejection because "the intended utility of 'introducing stem cells into a patient' is for the purposes of therapy or treatment." Applicants respectfully traverse this rejection.

In maintaining the original enablement rejection, the Office asks "for what purpose are these patients receiving stem cells, if not for treatment?" Applicants do not dispute that a reason a patient would receive stem cells is to replace cells that were lost or to repair damaged tissue. Notwithstanding this fact, as is indicated above, the current claims are explicitly directed to a method of introducing stem cells into a patient and the determination of enablement should be based on this limitation, not on the Office's perceived commercial use of the method. It is clear that the claims do not require amelioration of any disease or condition, and it is improper for the Office to impose this requirement in direct conflict with the plain words of the claims. The question of enablement must be focused on the words of the claims, and it is unquestioned that the specification enables the transplantation of cells into a patient. The Office so much as acknowledges that the specification enables the transplantation of cells into animals, noting that the specification discloses examples in which transplanted cells survived and differentiated in intact animals. This is all that the claims require.

In sum, Applicants submit that the claims are fully enabled by the specification. Accordingly, Applicants kindly request that the rejection under 35 U.S.C. § 112, first paragraph, be withdrawn.

#### <u>CONCLUSION</u>

Applicants submit that the claims are now in condition for allowance, and such action is respectfully requested.

Applicants note that the Form PTO 1449 that was submitted with an Information Disclosure Statement filed on December 4, 2002 has not been initialed and returned, and hereby request that it be initialed and returned. A copy of the submitted Form PTO 1449 is enclosed herewith.

Enclosed is a Petition to extend the period for replying to the Office action for three months, to and including December 21, 2005, and a check for \$510.00 for the fee required by 37 C.F.R. § 1.17(a). Further enclosed is a Notice of Appeal and a check for \$250.00 for the fee required by 37 C.F.R. § 41.20(b)(1).

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: 12/22/05

Kristina Bieker-Brady, Ph.D. Reg. No. 39,109

Michael J. Holliver, M.P. 12eg. No. 52,608

Clark & Elbing LLP 101 Federal Street Boston, MA 02110

Telephone: 617-428-0200

Facsimile: 617-428-7045